REMARKS

Entry of the foregoing and reconsideration of the application identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.111 and in light of the remarks which follow, are respectfully requested.

By the above amendments, claims 1-22 have been canceled without prejudice or disclaimer. New claims 23-42 have been added. Support for such new claims can be found at least at the following portions of the present specification:

claim 23	page 8, line 23 to page 9, line 8, taken in connection with page 6, lines 6-7; page 11, line 29 to page 12, line 5; page 12, lines 16-19; and page 18, line 28 to page 19, line 6;
claims 24 and 25	page 9, lines 17-24, taken in connection with page 8, lines 5-7;
claim 26	page 14, lines 9-16;
claim 27 and 40	page 11, lines 9-22;
claims 28 and 29	page 9, last line to page 10, line 6;
claims 30 and 31	page 14, line 30 to page 15, line 2;
claim 32	page 13, lines 9-16 and 26-28;
claims 33 and 34	page 12, line 30 to page 13, line 8;[1]
claim 35	page 12, lines 28-29;
claim 36 and 37	page 8, lines 5-17, taken in connection with page 6, lines 6-7; page 9, lines 17-24; page 10, lines 23-25; page 11, line 29 to page 12, line 5; page 12, lines 16-19; and page 18, line 28 to

[1] For clarification purposes, the formula of the phospholipid recited in claims 33 and 34 has been revised to explicitly show the fourth oxygen atom of such phospholipid. One skilled in the art would have recognized that Applicants were in possession of the recited formula in light of, for example, the discussion of phospholipids in *Lehninger*, "Biochemistry, The Molecular Basis of Cell Structure and Function," (second edition) Worth Publishers, Inc., page 288, a copy of which is attached hereto.

	page 19, line 6;
claims 38 and 39	page 10, lines 19-22; and
claims 41 and 42	page 9, last line to page 10, line 6.

In the Official Action, claims 1-22 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is moot in light of the cancellation of the rejected claims and as such, withdrawal of this rejection is respectfully requested.

Claims 1-5 and 9-12 stand rejected under 35 U.S.C. §102(b) as being anticipated by International Publication No. WO 00/16770. Claims 1-3, 6, 12-16 and 20-22 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,383,513 (*Watts et al*). Claims 1-12 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,997,888 (*Weder et al*). Claims 4-10, 12 and 16-22 stand rejected under 35 U.S.C. §103(a) as being obvious over *Watts et al.* Claim 11 stands rejected under 35 U.S.C. §103(a) as being obvious over *Watts et al* or *Weder et al*, further in view of U.S. Patent No. 5,004,611 (*Leigh*). Claims 1-22 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,616,334 (*Janoff et al*) in combination with *Leigh*. The above rejections are moot in light of the cancellation of the rejected claims.

Moreover, Applicants respectfully submit that newly added claims 23-42 are not anticipated by or rendered obvious over the above applied documents. In this regard, the applied documents fail to disclose or suggest a process for solubilizing a drug substance with low water solubility, comprising mixing: a) a first composition which is contained in a first container prior to mixing, comprising a drug substance with low water solubility, with b) a second composition which is contained in a second container prior to mixing, comprising a liposomal dispersion, as recited in independent claim 23. As well, the applied documents fail to disclose or suggest a kit for solubilizing a drug substance with low water solubility,

comprising: a) a first container containing a first composition comprising a drug substance with low water solubility, and b) a second container containing a second composition comprising a liposomal dispersion, as recited in each of independent claims 36 and 37. There is simply no disclosure or recognition of the use of first and second containers which contain a first composition comprising a drug substance with low water solubility and a second composition comprising a liposomal dispersion, respectively, prior to mixing.

Accordingly, for at least the above reasons, it is apparent that the applied documents neither anticipate nor render obvious the claims of the present application.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited. If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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BIOCHEMISTRY

SECOND EDITION

THE MOLECULAR BASIS

OF CELL STRUCTURE AND FUNCTION

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and electric charge of their polar head groups (Table 11-5 and Figures 11-11 and 11-12). Each type of phosphoglyceride can exist in many different chemical species differing in their fatty acid substituents. Usually there is one saturated and one unsaturated fatty acid, the latter in the 2 position of glycerol.

The parent compound of the phosphoglycerides is *phosphatidic acid* (Figure 11-10), which contains no polar alcohol head group. It occurs in only very small amounts in cells, but it is an important intermediate in the biosynthesis of the phosphoglycerides. The most abundant phosphoglycerides in higher plants and animals are *phosphatidylethanolamine* and *phosphatidylcholine* (Table 11-5 and Figure 11-12), which contain as head groups the amino alcohols *ethanolamine* and *choline*, respectively. (The new names recommended for these phosphoglycerides are *ethanolamine phosphoglyceride* and *choline phosphoglyceride*, but they have not yet gained wide use. The old trivial names are cephalin and lecithin, respectively.) These two phosphoglycerides are major components of most animal cell membranes.

In *phosphatidylserine*, the hydroxyl group of the amino acid L-serine is esterified to the phosphoric acid. In *phosphatidylinositol*, the head group is the six-carbon cyclic sugar alcohol inositol. In *phosphatidylglycerol*, the head group is a molecule of glycerol. Phosphatidylglycerol is often found in bacterial membranes as an amino acid derivative, particularly of L-lysine, which is esterified at the 3′ position of the glycerol head group. This type of amino acid–containing lipid is called a *lipoamino acid* or, more accurately, an *O-aminoacylphosphatidylglycerol* (see Table 11-5).

Closely related to phosphatidylglycerol is the more complex lipid *cardiolipin*, also called *diphosphatidylglycerol*, which consists of a molecule of phosphatidylglycerol in which the 3′-hydroxyl group of the second glycerol moiety is esterified to the phosphate group of a molecule of phosphatidic acid (Figure 11-12 and Table 11-5). The backbone of cardiolipin thus consists of three molecules of glycerol joined by two phosphodiester bridges; the two hydroxyl groups of both external glycerol molecules are esterified with fatty acids. Phosphatidylglycerol, O-aminoacylphosphatidylglycerol, and cardiolipin are therefore structurally related. They are characteristically abundant in the cell membranes of bacteria. Cardiolipin is also present in large amounts in the inner membrane of mitochondria; it was first isolated from heart muscle, in which mitochondria are abundant.

The polar head groups of phosphatides may also be contributed by a sugar molecule. Phosphatidyl sugars have been found in plants and microorganisms. They are not to be confused with other types of glycolipids containing no phosphoric acid.

Plasmalogens differ from all the other phosphoglycerides described above. One of the two hydrocarbon tails is contributed by a long-chain fatty acid esterified to the 2 position of the glycerol, but the other is a long aliphatic chain in cis

Figure 11-11
General structure of phosphogly[...] form emphasizing their amphip[...] Usually the fatty acid in the 2 p[...] unsaturated.